REMARKS

Claims 1-19, 21-27, and 29-31 are in the case. Claims 20 and 28 have been cancelled. Claims 30 and 31 have been added. No new matter has been added.

Claim 20, which has been rejected as being directed to non-statutory subject matter, has been cancelled, thereby obviating this rejection.

Claims 1-19 and 24 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner states that the claims "are generally narrative and indefinite" and fail to conform with current U.S. practice. It is believed that the amendments to the claims overcome this rejection and place the claims in proper form for further examination.

The Claimed Invention

As now more clearly claimed, Applicant's invention features, in one aspect (recited in amended claim1), a biopsy instrument for sampling bone marrow tissue, including a handle for inserting the instrument into the tissue, and, coupled to the handle, a single hollow tube, configured for both cutting and receiving a tissue sample. The tube has (a) a bore defining a tissue-receiving space for said tissue sample, (b) a substantially rigid tip, and (c) an outer wall configured to contact the tissue. The outer wall is provided with an abrading formation extending in an axial direction along the tube to abrade the tissue, and thereby to allow the tip of the tube to be laterally displaced within the bone marrow tissue to facilitate retrieval of a tissue sample. Using the biopsy instrument, a relatively large diameter sample can be obtained. Furthermore, retrieval of the sample may be achieved without substantial compression of the sample, and thus generally without undesirable distortion of the sample.

In another aspect, recited in amended claim 21, Applicant's invention features a method of sampling a substance using a needle, the needle having a handle coupled to a sampling member, the sampling member including a sampling tip with a bore therein to receive a sample of the substance, the sampling tip having a formation on its outer surface for abrading the substance. The method includes (a) inserting the sampling tip into the substance to be sampled to collect a sample within the bore of the sampling tip; (b) gyrating the sampling tip so that the

substance is abraded, to allow the sampling tip to be displaced laterally sufficiently to weaken a connection between the sample and the bulk of the substance; and (c) withdrawing the sampling tip with the sample therein.

In yet another aspect, recited in claim 22, the invention features a biopsy needle for sampling bone marrow tissue, including (a) a tissue sampling member including a sampling tube with a bore therein to receive a tissue sample; (b) a handle connected to the tissue sampling member for manual insertion of the biopsy needle; and (c) a coupling member, detachably connected to the tissue sampling member, for coupling the needle to a rotary motor drive, so that the needle is adapted for both manual insertion and motor-assisted insertion.

The invention also features the biopsy needle assembly having the features recited in claim 29.

Rejections Under 35 U.S.C. §102(b)

Claims 1-4, 6, 15, 16, 19 and 21 have been rejected as being anticipated by Baldridge. Claims 22-28 have been rejected as being anticipated by Kedem.

With regard to claim 1, Baldridge does not teach or fairly suggest a biopsy instrument having a single hollow tube, configured for both cutting and receiving a tissue sample, the tube having (a) a bore defining a tissue-receiving space for the sample, (b) a substantially rigid tip, and (c) an outer wall configured to contact said sampled tissue, provided with an abrading formation extending in an axial direction along the tube to abrade the sampled tissue.

Instead, Baldwin discloses an instrument having a double tube structure, in which an outer tube is used to drill through the surface of a bone into the marrow, and an inner tube with pincers is used to collect a biopsy sample (see, e.g., Figs. 9-12 and col. 2, lines 49-56, col. 3, lines 3-7 and 24-43, col. 4, lines 7-16, col. 5, lines 50-54, col. 6, lines 16-26 and 47-50, and col. 7, lines 57-63). Using the Baldridge device, the tissue sample is retrieved using the inner tube pincers, rather than by laterally displacing the tip of a tube as recited in Applicant's claims. In fact, Baldridge expressly teaches that it is important to eliminate the need to tilt the needle to break the bone marrow sample free (col. 4, lines 12-16; col. 2, lines 32-35).

Applicant respectfully disagrees with the Examiner's reading of Baldridge. In particular, there is no disclosure of a slot with at least one sharpened edge or with both outer edges

sharpened. The Baldridge device has a slot cut at the end of the inner needle in order to allow this needle to be deformed (as shown, for example, in Fig. 10 of Baldridge), to capture a sample within the needle. However, this slot is inside the outer needle and is incapable of performing the cutting or abrading function claimed by Applicant.

With regard to claim 21, Baldridge does not teach or fairly suggest abrasion of bone tissue. Use of the Baldridge device does not involve "gyrating the sampling tip so that the substance is abraded, to allow the sampling tip to be displaced laterally sufficiently to weaken a connection between the sample and the bulk of the substance" as claimed. Instead, the steps illustrated in Baldridge's Figs. 9-12 involve a compression and cutting action. Moreover, as discussed above, Baldridge expressly teaches away from lateral displacement of the sampling tip.

With regard to claim 22, the instrument disclosed by Kedem lacks a coupling that is detachably connected to a tissue sampling member, as required by claim 22. Kedem's inner hollow needle 6, which is used for tissue sampling (see, e.g., col. 5, lines 6-8), is coupled to motor 4 by a coupling member 26 (col. 3, lines 54-62). Although this coupling member may be detachable from motor 4, there is no teaching or suggestion that the coupling member be detachably connected to the inner hollow needle 6. The instrument described in Kedem also lacks the handle recited in Applicant's claim 22 (see, for example, col. 4, lines 50-52).

Claims 2-4, 6, 15, 16 and 19 all depend from claim 1, and claims 23-28 depend from claim 22, and thus these claims are allowable over the prior art on the basis of the arguments presented above. As a result, the examiner's comments and objections specific to these dependent claims are rendered moot and therefore have not been addressed. However, Applicant reserves the right to do so.

Rejections Under 35 U.S.C. §103

Claims 13, 14, 17, 18 and 29 have been rejected as obvious over Baldridge in view of Kedem. Claim 5 has been rejected as obvious over Baldridge in view of Mittermeier.

With regard to claims 5, 13, 14, 17 and 18, Applicant respectfully submits that these claims are patentable for at least the reasons discussed above with respect to claim 1. Neither Kedem nor Mittermeier supplies that which is lacking in Baldridge, i.e., a teaching or suggestion of a biopsy instrument having a single hollow tube, configured for both cutting and receiving a

tissue sample, having (a) a bore defining a tissue-receiving space for the sample, (b) a substantially rigid tip, and (c) an outer wall configured to contact the tissue, provided with an abrading formation extending in an axial direction along the tube to abrade the tissue.

In the Kedem instrument, the outer surface of inner hollow needle 6 (the needle that samples the tissue) is not in contact with tissue – instead, it is sheathed within the outer hollow needle 8 (col. 2, lines 40-43 and col. 4, lines 46-49). Mittermeier also fails to disclose a tissue sampling tube with an abrading formation on its outer surface.

Thus, claims 5, 13, 14, 17 and 18 are allowable over the prior art on the basis of the arguments presented above with regard to claim 1. As a result, the examiner's comments and objections specific to claims 5, 13, 14, 17 and 18 are rendered moot and therefore have not been addressed. However, Applicant reserves the right to do so.

Claim 29 includes a number of features that are neither disclosed nor suggested by the prior art, including: a single cannula with a recess or recesses on its outer surface at the distal end and an expansion on the outer surface at the distal end; a connector attachment with a knob sized to fit within an orifice so that force may be rotatably applied, the knob being sized to fit an electric drill or screwdriver; and a sheath sized to fit around the electric drill or screwdriver.

In view of the above remarks, Applicant respectfully submits that all claims are in condition for allowance.